DETAILED ACTION

Receipt is acknowledged of an amendment, filed 3/22/2011, in which claims 8, 12, 22 and 23 were amended, and claims 26-39 were newly added. Claims 7, 8, 11, 12, 22, 23 and 26-39 are pending.

The amendment to the claims filed on 3/22/2011 does not comply with the requirements of 37 CFR 1.121(c) because all claims do not have the proper status identifier. Specifically, claim 7 has the status identifier "Currently amended"; however, the markings shown in the claim were also present in the claim set filed 12/21/2009. Thus, the markings do not show changes relative to the immediate prior version of the claim, and the claim should have the status identifier "Previously presented." See 37 CFR 1.121(c). In the interest of compact prosecution, the amendment has been entered. In response to this action, Applicant must provide a claim listing in compliance with 37 CFR 1.121(c).

Election/Restrictions

Applicant elected Group IV with traverse in the reply filed on 7/11/2008. Claims 7, 8, 11, 12, 22, 23 and 26-39 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8, 11, 12, 22, 23 and 26-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection was made over claims 7, 8, 11, 12, 22 and 23 in the prior action and has been extended to new claims 26-39, which were added in the reply filed 3/22/2011.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: Claim 7 is drawn to a method of reducing a bacterial population in a subject in need of treatment. The method comprises the step of administering a therapeutically effective amount of a composition comprising an isolated phage tail that inhibits the growth of a target bacterium, thereby reducing the growth of the bacterial population. The specification teaches that "growth inhibition" encompasses slowing the rate of bacterial cell division, stopping bacterial cell division, or killing the bacteria (e.g., paragraph [0048]). Claim 8 depends from claim 7 and requires that said subject is a human. Claim 26 requires that said subject is a primate, a food, work, display or companion animal. Claim 27 requires that said target bacterium is *Escherichia, Staphylococcus, Pseudomonoas,* or *Streptococcus*. Claim 28 requires that said method further comprises administering a second therapeutic or antimicrobial agent. Claim 29 requires that said method results in a relative decrease in said population of at

least 10-1000 fold. Claim 30 requires that said method results in a decrease in detectability of said population by at least 5-50 fold. The nature of the invention is complex in that the administration of the phage tail must inhibit the growth of a target bacterium, thereby reducing the growth of the bacterial population, including the specific bacterial populations and levels of reduction recited in claims 29 and 30.

Claim 11 is drawn to a method of treating a bacterial infection in a subject in need of such treatment. The method comprises the step of administering a therapeutically effective amount of a pharmaceutical composition comprising an isolated phage tail, wherein said isolated phage tail inhibits the growth of a target bacterium, thereby treating the bacterial infection. Claim 12 depends from claim 11 and requires that said subject is a human. Claim 31 requires that said subject is a primate, a food, work, display or companion animal. Claim 32 requires that said pharmaceutical composition is administered systemically, parenterally, orally, topically, or by inhalation, catheter, or drain tube. Claim 33 requires that said pharmaceutical composition is administered in combination with a second therapeutic selected from an anti-microbial and an anti-inflammatory agent. The nature of the invention is complex in that the administration of the phage tail must inhibit the growth of a target bacterium, thereby reducing the growth of the bacterial population and treating the existing infection.

Claim 22 is drawn to a method of treating a bacterial colonization in a subject experiencing colonization by a target bacterium. The method comprises the step of administering to the subject a defined dose therapeutic anti-bacterial composition comprising an isolated phage tail, thereby treating the bacterial colonization. Claim 23 depends from claim 22 and requires that said subject is a food, work, display or companion animal. Claim 34 requires

that said subject is a human. Claim 35 requires that said target bacterium is a pathogenic, nosocomial, or pyogenic bacterium. Claim 36 requires that said target bacterium is an *Escherichia, Staphylococcus, Pseudomonas,* or *Streptococcus* bacterium. Claim 37 requires that the colonization has already been treated with an anti-microbial or antibiotic. Claim 38 requires that said composition is administered systemically, parenterally, orally, topically, or by inhalation, catheter, or drain tube. Claim 39 requires that said target bacterium has been diagnosed to be susceptible to the selected composition. The nature of the invention is complex in that the administration of the phage tail must inhibit the growth of a target bacterium, thereby reducing the growth of the bacterial population and treating the existing infection.

Breadth of the claims: The claims are broadly drawn to the administration of any isolated phage tail from any phage. Further, the claims are broadly drawn to reducing the growth and treating the infection of any bacterial species. Moreover, the claims are drawn to treating an infection in any subject. The specification defines "subject in need of treatment" as an animal or plant with a bacterial infection that is potentially life-threatening or that impairs health or shortens the lifespan of the animal (e.g., paragraph [0059]). The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the specification and existence of working examples: The specification teaches that a tailed bacteriophage generally comprises a head, called the capsid, and a tail (e.g., paragraph [0007]). The tail structure has a tube, a sheath covering the tube, tail fibers and a base plate, where each of the structures is made of or contains different proteins (e.g., paragraph [0113]). The specification teaches that phage tail and phage tail-like structures can be similarly described as bacteriophage structures that are essentially devoid of phage DNA (and phage

replication) while retaining killing function (e.g., paragraph [0007]). Further, the specification teaches that pyocins are "believed to be tail-like portions of tailed phages" (paragraph [0008]). The specification provides general methods for the production of phage tail (e.g., paragraphs [0157]-[0158]).

The specification envisions treating a bacterial infection in a subject by administering an anti-bacterial phage fragment, such as a phage tail (e.g., paragraphs [0021] and [0045]). The specification envisions using the tailed portion of a phage from the Siphoviridae or Myoviridae families (e.g., paragraph [0042]) to treat infections of gram negative or gram positive bacteria (e.g., paragraph [0095]). The specification envisions determining by an *in vitro* assay the "killing units" of the composition to be administered to the subject and formulating the composition for delivery by an intravenous, intramuscular, intraperitoneal, intrathecal, vaginal, rectal, topical, lumbar puncture, direct application to the brain and/or meninges, etc. (e.g., paragraphs [0130]-[0143]).

The specification does not contain any working examples of the claimed invention. The working examples are limited to testing the *in vitro* activity of the P9042 and P954 phage tails. The specification teaches that P9042 and P954 are examples of phages that were isolated from nature and are capable of being propagated in *Staphylococcus aureus* (e.g., paragraph [0163]). P9042 is a lytic phage, and P954 is a lysogenic phage (e.g., paragraph [0163]). In Example 2, the killing activity of P9042 tails was determined using *Staphylococcus simulans* as the target. The P9042 phage tails were capable of killing *Staphylococcus simulans* (e.g., paragraph [0170]). In Example 3, the killing activity of P954 tails was determined using *S. aureus* B935 as the target. The phage tails were able to kill *S. aureus* B935 (e.g., paragraph [0183]). Further, the

specification teaches that *S. aureus* strains B935, B904, B913, B920, B903, B975, and B972 each harbor receptors for attachment of phage P954 (e.g., paragraph [0184]). These strains were tested for P954 phage tail-based killing and each was susceptible (e.g., paragraph [0188]). The ability of the P954 phage tail to kill *S. aureus* B935 was confirmed in Example 4. Under the disclosed *in vitro* assay conditions, tail killing activity started as early as 10 min, whereas the doubling time of the bacteria was about 25 min (e.g., paragraph [0194]). Furthermore, the P954 tail preparations were tested against 33 clinical isolates of *Staphylococcus aureus* collected from hospitals in Bangalore, India (e.g., paragraph [0200]). The tail preparation was capable of killing >80% isolates, whereas the whole phage was capable of killing only about 12% of the isolates (e.g., paragraph [0201]). Example 5 demonstrates that the P9042 tails were not inactivated with trypsin but were unstable after heat treatment, whereas P954 tails were sensitive to trypsin (e.g., paragraph [0205]). No working examples are provided where phage tail killing activity was determined *in vivo*. Phage tails were not administered to subjects or eukaryotes infected with bacteria. In summary, the specification provides evidence that the P954 and P9042 phage tails are capable of killing *Staphylococcus simulans* and *Staphylococcus aureus in vitro*.

The description of the specification does not provide support for the administration of an anti-inflammatory agent to reduce bacterial growth or treat a bacterial infection.

Predictability and state of the art: It would have been unpredictable to extrapolate the *in vitro* bacterial killing activity of phage tail preparations to the treatment of bacterial infections in subjects *in vivo*. While the prior art does not specifically test the correlation between *in vitro* and *in vivo* activity of phage tails *per se*, the prior art does assess the ability of pyocins, which are phage tail-like preparations (e.g., specification at paragraph [0008]). Furthermore, the prior art

has considered the *in vitro* killing activity of phage tail to be similar to that of R-type pyocins (Shinomiya et al. Journal of Virology, Vol. 32, No. 3, pages 958-967, December 1979, cited in a prior action; e.g., page 966, left column).

Merrikin et al (Applied Microbiology, Vol. 23, No. 1, pages 164-165, January 1972, cited in a prior action) teach that pyocin 78-C2 is not effective in treating existing *Pseudomonas aeruginosa* infection in mice. Pyocin was effective against strain 320 when administered intravenously immediately after infection or intravenously 6 hours after infection (e.g., page 164, paragraph bridging columns, and right column, 2nd full paragraph). Pyocin was effective against strain 325 when administered intravenously immediately after infection (e.g., page 164, paragraph bridging columns, and right column, 2nd full paragraph). However, pyocin was not effective against either of these strains when administered intravenously 24 hours after infection (e.g., page 164, paragraph bridging columns, and right column, 2nd full paragraph). Moreover, pyocin was not effective in any administration schedule against strain 327 even though the strain is sensitive to pyocin *in vitro* (e.g., page 164, right column, 2nd full paragraph). Thus, Merrikin et al teach that the effectiveness of pyocin *in vitro* does not always correlate to the effectiveness *in vivo*, and for the pyocin to be effective *in vivo* it must be administered within 6 hours of infection.

Similarly, Haas et al (The Journal of Infectious Diseases, Vol. 129, No. 4, pages 470-472, April 1974, cited in a prior action) teaches that a pyocin with lytic activity *in vitro* against sensitive strains at dilutions of 1:1,000 had no effect on the mortality of mice infected with a sensitive *P. aeruginosa* strain when the pyocin was administered after bacterial infection of the mouse (e.g., page 470, right column; Table 1).

Williams (Journal of Medical Microbiology, Vol. 9, pages 153-161, 1976, cited in a prior action) teaches the production of pyocins from *P. aeruginosa* strains 1577, 5882 and H108, which were described as contractile, filamentous, and small, respectively (e.g., page 154, *Selection of pyogenic strains*). Each of the pyocins had activity against *P. aeruginosa* strain P14 *in vitro* (e.g., page 154, 3rd full paragraph). Williams teaches that mice that received bacteria before the injection of pyocin died (pyocin administered 3 or 6 hr after bacteria), whereas mice that received pyocin before or along with the bacteria had a considerably lower mortality (e.g., page 157, last paragraph; Table III; page 159, 3rd full paragraph). Further, Williams teaches that pyocin administration to burned mice did not reduce the growth of *P. aeruginosa* on the burn (e.g., page 158, 3rd and 4th paragraphs). Williams concludes that the outlook for pyocin therapy is not favorable (e.g., page 160, 4th paragraph).

In sum, the prior art teaches that pyocins are not effective for reducing bacterial growth and treating an existing bacterial infection *in vivo*. Further, phage tails kill by a single-hit process but are less effective at killing *in vitro* as compared to pyocins (Shinomiya et al. page 966, left column, last full paragraph). Thus, one would not have an expectation of success in extrapolating results from *in vitro* killing assays to *in vivo* methods of reducing bacterial growth and treating bacterial infections by administering an isolated phage tail.

The post-filing art teaches that the *in vivo* susceptibility of bacteria to bacteriophages is still largely poorly understood, and further research on phage-bacterium systems must be undertaken to define the requirements for successful phage treatments (Skurnik et al. International Journal of Medical Microbiology, Vol. 296, pages 5-14, February 2006, cited in a prior action; e.g., Abstract; page 11, Conclusions). Further, Skurnik et al teach that the use of

phage tail-like bacteriocins (pyocins) as antimicrobial agents most likely will be limited only to *in vitro* applications (e.g., paragraph bridging pages 8-9). The tail-like structures are only effective when administered immediately after infection (Skurnik et al. paragraph bridging pages 8-9; Merrikin et al. page 164, paragraph bridging columns, and right column, 2nd full paragraph; Haas et al. page 470, right column; Table 1). Thus, the phage tail is likely only to be effective in experimental models where the phage tail is administered prior to a known time point of infection or at the same time as experimentally induced infection. It would be unpredictable to use phage tail to reduce bacterial growth in an existing infection in a eukaryotic organism.

Amount of experimentation necessary: In view of the unpredictable nature of the invention, the quantity of experimentation would be large. One would be required to test each phage tail from a particular phage for the ability to reduce bacterial growth of a specific bacterial species and strain *in vivo*. The effectiveness of one phage tail with one particular strain *in vivo* would not provide any estimation of effectiveness of the same phage tail against another strain or a different phage tail against the same strain.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 7, 8, 11, 12, 22, 23 and 26-39 are not considered to be enabled by the instant specification.

Response to Arguments - 35 USC § 112

With respect to the rejection of claims 7, 8, 11, 12, 22, 23 and 26-39 under 35 U.S.C. 112, first paragraph, Applicant's arguments filed 3/22/2011 have been fully considered but they are not persuasive.

The response asserts that phage tails are not pyocins and the direct comparison to the killing activity of pyocins is not valid, and the cited pyocin references do not cast doubt on the claimed methods. The response asserts that pyocins and phage tails are structurally distinct. Further, the response asserts that the references cited by the examiner essentially provide a snapshot of the state of the art 35 years ago for therapeutic use of pyocins.

These arguments are not found persuasive. The specification states, "phage tail and phage tail like structures can be **similarly described** as bacteriophage structures that are essentially devoid of phage DNA." (emphasis added) See paragraph [0007]. Further, the specification teaches that pyocins are "believed to be tail-like portions of tailed phages" (paragraph [0008]). In the reply filed 12/21/2009, Applicant summarizes the art as teaching that "**pyocins are not effective for treating an existing infection** *in vivo*, and that **phage tails are much less efficient antibacterial agents than pyocins** for killing bacteria *in vitro*." See page 9 of 11 of the reply filed 12/21/2009. The post-filing art teaches that the *in vivo* susceptibility of bacteria to bacteriophages is still largely poorly understood, and further research on phage-bacterium systems must be undertaken to define the requirements for successful phage treatments (Skurnik et al. International Journal of Medical Microbiology, Vol. 296, pages 5-14, February 2006, cited in a prior action; e.g., Abstract; page 11, Conclusions). Accordingly, it

would have been unpredictable to use phage tail to reduce bacterial growth, treat a bacterial infection, or treat a bacterial colonization in a subject at the time the invention was made.

The response asserts that the cited art does not invalidate the correlation between *in vivo* and *in vitro* killing activity. The response asserts that pyocins have been shown to effectively protect animals from bacterial infections as long as the pyocins are administered soon after challenge. Further, the response asserts that one of skill in the art would have understood that treatment of existing infections would require higher doses of phage tail. The response asserts that the references do not cast doubt on the idea that a higher doses of pyocin may be effective for treating an existing bacterial infection *in vivo*, because the references do not describe the use of sufficiently high doses of pyocins to be effective at later time points in the bacterial infection. Further, the response asserts that "tail-like" structures are structurally and functionally distinct from phage tails. Applicant discusses the references cited by the Examiner.

These arguments are not found persuasive. As noted above, the specification teaches that pyocins and phage tails are structurally and functionally similar. This assertion is supported by the teachings of Shinomiya et al (1979). Shinomiya states, "The results confirmed the close relationship between PS17 and R-type pyocins, which had been suggested in previous reports on the basis of serological and morphological evidence." (Citations omitted) See page 966, left column, 1st full paragraph. Shinomiya goes on to state, "The results in this article agree with the idea that phage PS17 is closely related to R-type pyocins on the basis of its structure and of the mode of its action; but it seems unlikely that the R-type pyocins are defective phages directly derived from PS17, because there are distinct differences between the structure of these pyocins and that of the PS17 tail." See page 966, right column, 1st full paragraph. In answer to

Applicant's newly cast doubt of the "close relationship" taught by Shinomiya et al, further evidence of similarity of PS17 and R-type pyocins is provided by Shinomiya et al (Journal of Bacteriology, Vol. 171, No. 5, pages 2287-2292, May 1989). Shinomiya et al (1989) teach that PS17 and R-type pyocins most likely share a common ancestor (e.g., page 2287, left column, 1st paragraph). The tail genes of PS17 and the R-type pyocin genes form a cluster similar in size (e.g., page 2291, right column, 3rd full paragraph). Furthermore, Shinomiya et al (1989) teach that certain PS17 genes and pyocin R2 genes are exchangeable in function (e.g., page 2291, paragraph bridging columns). Specifically, the sheath genes of PS17 and the R-type pyocins must be homologous, because they were immunologically cross-reactive, hybridized to one another, and could complement each other (e.g., page 2291, right column, last full paragraph). Shinomiya et al conclude that at least six genes of PS17 tail and R-type pyocins are related with respect to immunological cross-reactions of products, functional exchangeability or both (e.g., page 2292, left column, 2nd full paragraph). Thus, the statements by Shinomiya et al (1979) regarding the close relationship of PS17 and R-type pyocins are accurate. The teachings of Shinomiya et al (1979) regarding the reduced efficiency of PS17 phage tail as compared to R-type pyocin effectively cast doubt on the ability of one skilled in the art to carry out the claimed invention at the time the invention was made. Furthermore, the art of record does not teach a dose of pyocin effective to treat an existing infection, and Shinomiya et al (1979) teach that phage tail is less effective than pyocin. Thus, one would not expect phage tail to be effective in treating an existing infection. No working examples of the claimed invention are disclosed in the specification, and Applicant has not provided objective evidence to demonstrate the unexpected effectiveness of phage tails *in vivo*. It would have been unpredictable to treat existing infections

with increased amounts of pyocin or phage tail proteins. There is no evidence on the record that provides evidence that such an approach would have been successful.

The response asserts that the present inventors solved the problem the problem treating established bacterial infections when the phage tail is provided in sufficient quantities. The response states that the concept of providing a dose of phage tail commensurate with the bacterial population is presented at paragraphs [0041]-[0042] and [0130] of the specification. The response notes that the prior art dose at which bacteria are effectively killed *in vitro* does not provide a dose effective for eliminating established infections *in vivo* comprising a larger, expanding bacterial infection. The response asserts that the Examples disclosed in the specification show that phage tails from different parent phage can effectively kill multiple bacterial strains *in vitro*. The response asserts that one would have no reason to doubt that an appropriate dose of phage tails could reduce a bacterial population *in vivo*.

This argument is not persuasive. There is no working example in the present specification, which demonstrates the successful treatment of an existing bacterial infection *in vivo*. The statements made in the reply regarding the effectiveness in treating established bacterial infections are not supported by the objective evidence on the record. One would have reason to doubt that an appropriate dose of phage tails could reduce a bacterial population *in vivo*, because the prior art teaches that pyocins are not effective *in vivo*, and phage tails are less effective than pyocins *in vitro* (Shinomiya et al, 1979). No prior art demonstrates the effective treatment of an existing bacterial infection with pyocins of a higher dose or with any dose of phage tail. The post-filing art teaches that the *in vivo* susceptibility of bacteria to bacteriophages is still largely poorly understood, and further research on phage-bacterium systems must be

undertaken to define the requirements for successful phage treatments (Skurnik et al. International Journal of Medical Microbiology, Vol. 296, pages 5-14, February 2006, cited in a prior action; e.g., Abstract; page 11, Conclusions). Accordingly, it would have been unpredictable to use phage tail to reduce bacterial growth of an existing infection in a subject at the time the invention was made.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 8, 11, 12, 22, 23, 26, 28-35 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 9-16 and 20-24 of copending Application No. 11/915,272. This rejection was made in the Office action mailed 11/22/2010 and has been rewritten to address the amendments to the claims in the present application, filed 3/22/2011, and the amendments to the claims in the '272 application, filed 4/4/2011 (specifically, the cancellation of claims 8 and 19).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a phage tail to reduce a pathogenic bacterial population in an animal, such as a human or food animal, where the phage tail is administered with a second anti-microbial ingredient (e.g., controlled release bacteriophage of the '272 application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments - Double Patenting

With respect to the provisional rejection of claims 7, 8, 11, 12, 22, 23, 26, 28-35 and 38 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 9-16 and 20-24 of copending Application No. 11/915,272, Applicant's arguments filed 3/22/2011 have been fully considered but they are not persuasive.

The response notes that the claims of the '272 application and the present application have yet to be finalized. The response states that Applicants will consider filing a terminal disclaimer once the pending claims are considered otherwise allowable.

Because Applicant has not overcome the rejection by amendment, argument or filing a proper terminal disclaimer, the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is (571)272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Dunston/
Primary Examiner
Art Unit 1636